REMARKS

Claims 1, 2, 6-26 and 30-33 are currently pending in this application. Applicants respectfully traverse the rejections of the claims. In view of the remarks to follow, reconsideration and allowance of this application are respectfully requested.

In the Office Action, Claims 1, 2 and 6-17 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,665,073 to Bulow et al. ("Bulow"). Under 35 U.S.C. § 102(b), "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. Applicants respectfully submit that Bulow fails to disclose each and every element recited in independent Claim 1, either expressly or inherently.

Bulow discloses a protective sheath and securement apparatus for surgical conduits shown in FIGS. 3 and 4 below. The apparatus of Bulow includes a fabric sleeve 12, a shield 14 mounted to the distal end of the sleeve 12, and a sheath guide 70 configured for deploying sleeve 12. Guide 70 includes opposed guide members 72 and 73. Each guide member 72, 73 includes a semicylindrical surface 74, 75, respectively, and a semicircular flange 76, 77, respectively. Semicircular flanges 76, 77 collectively provide a bonding surface for bonding a distal end 13 of fabric sleeve 12 to shield 14. In particular and with specific reference to FIG. 4, distal end 13 of fabric sleeve 12 to be bonded to shield 14 is shown by a broken line at 13a while a bonding surface 15 on shield 14 to which distal end 13 is to be bonded is delineated by a broken line 15a. Semicircular flanges 76, 77 in effect sandwich distal end 13 against bonding surface 15 to present to the user of protective sheath 10 a smooth profile through which

collective conduits 60 can be passed. Semicircular flanges 76, 77 also secure retainer strings 18, 19 to sheath 14. Guide member 70 serves as a basal element over which fabric sleeve 12 can be telescopically folded.

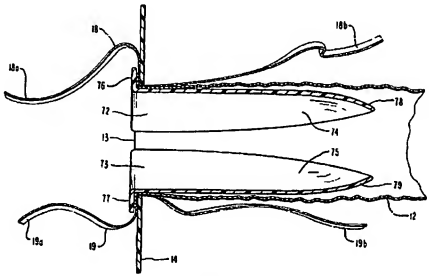


FIG. 3

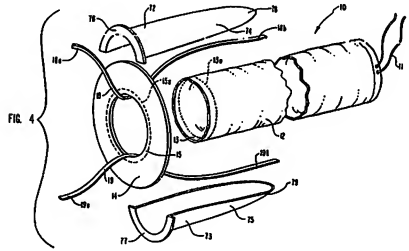


FIG. 4

With reference to FIG. 1 of Bulow, below, in use, conduits 32, 42, 52 (collectively, conduits 60) are inserted through shield 14 and fabric sleeve 12 and a drawstring 11 is tied

about the conduits. Next, shield 14 and guide 70 are moved along the conduits (in a direction away from drawstring 11) to unfold fabric sleeve 12 about the conduits. Sleeve 10 is then secured to a surgical drape 24 using hemostats 26. Protective sleeve 10 functions to protect the conduits from liquids to facilitate cleanup upon completion of the surgical procedure. Following completion of the surgical procedure, drawstring 11 is released and conduits 32, 42 and 52 are individually pulled through fabric sleeve 12 and shield 14.

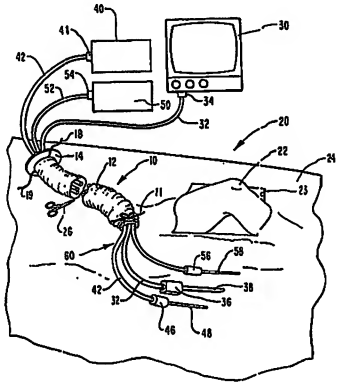


FIG. 1

Applicants respectfully submit that Bulow fails to disclose the surgical instrument recited in Claim 1. More specifically, Bulow fails to disclose the following elements recited in Claim 1:

1) "an elongated cover supported about the body portion of an instrument"

2) "the elongated cover being movable about the body portion of the instrument from a first position located proximally of the tool assembly to a second position at least partially encompassing the tool assembly;

3) "...the distal end of the elongated cover is secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly..."; and

4) "a cover deployment device at least partially disposed about the body portion [of the surgical instrument] between the body portion and the elongated cover when the cover is in the first position, the cover deployment device being in releasable engagement with the cover and being advanceable along the body portion to move the cover from the first position to the second position."

In contrast to the surgical instrument recited in Claim 1, Bulow's protective sheath is not supported about, nor does it function to protect or shield a surgical instrument having a tool assembly. Rather, Bulow's sheath shields hoses or conduits for supplying air, water, power, etc. to a surgical site. Thus, Bulow's sheath is not supported about the body portion of an instrument.

The sheath of Bulow is not movable about the body portion of an instrument from a first position located proximal of the tool assembly to a second position at least partially encompassing the tool assembly. As discussed above, Bulow's sheath is not received about the body portion of an instrument, and therefore, cannot not be moved from such a position located proximal of the tool assembly to a second position at least partially encompassing the tool assembly.

As discussed in detail above, the distal end of Bulow's sheath is not secured to a surgical instrument adjacent a tool assembly, but rather is secured about a plurality of hoses 60 and to a surgical drape 24 to effectively orient the conduits. Since Bulow's guide 70 is fixedly secured to sleeve 12, sleeve 12 cannot be inverted about a tool assembly. As such, the distal end of Bulow's sheath is not secured to the instrument adjacent to the tool assembly such that the elongated cover can be inverted about the tool assembly.

In addition, Bulow's guide 70 is not in releasable engagement with the sheath and therefore is not advanceable along a body portion of a surgical instrument to move the sheath along the body from the first position to the second position, where the sheath is at least partially covering the tool assembly. In contrast, Bulow operates by first advancing guide 70 about hoses 60 to a position closer to the surgical site, cinching the drawstring 11, and then pulling guide 70 away from the surgical site to deploy sleeve 12 about the hoses.

In the Office Action, the Examiner stated the following:

> Guide member 72 and 73 can be considered as cover deployment device which are between the cover and body portion(s) and which are in releasable engagement with the cover. When members 18 and 19 are released as in Figure 1 and the drawstring 11 is secured to the body portion adjacent the tool assemblies (which would be a reasonable configuration for this apparatus), the cover deployment device could be advanced along the body portion to move the cover from the first position to the second position.

As discussed in Applicants previous response, and contrary to the Examiner's statements in the Office Action, Bulow does not disclose a deployment device which is in releasable engagement with the cover. Bulow's sheath guide 70 includes opposed guide members 72, 73, which the Examiner identified as the cover deployment device, each of which include a semicircular flange 76, 77, respectively. Semicircular flanges 76, 77 collectively provide a bonding surface

for fixedly bonding a distal end 13 of fabric sleeve 12 to shield 14. In a first or retracted configuration, sleeve 12 is completely received about and supported on guide members 72, 73. In the second or deployed configuration, the distal end 13 of sleeve 12 is received about and supported on guide member 72, 73. At all times, distal end 13 of sleeve 12 is fixedly secured to guide members 72, 73. Thus, Bulow's sleeve 12 is fixedly secured to guide 70, and is not releasably engaged with the cover as recited in Claim 1.

Applicant notes that the presently claimed instrument including the cover and cover deployment device is provided to manipulate, identify, treat, repair and/or excise tissue within a body cavity. The cover and cover deployment device of the instrument are provided to deploy and shield a tool assembly of the instrument, which may have contacted diseased tissue during a surgical procedure, after the tool assembly has been used within the body cavity and prior to removal of the instrument/tool assembly from the body cavity. The releasablity of the cover from the cover deployment device, as recited in Claim 1, facilitates effective use of the cover in such an environment.

For the reasons discussed above, Bulow does not even remotely teach or suggest the surgical instrument recited in Claim 1. Thus, for any or all of the reasons discussed above, Claim 1 is patentable over Bulow and is in condition for allowance.

Claims 2, 3 and 5-17 depend either directly or indirectly from Claim 1. For at least the reasons discussed above with respect to Claim 1, inter alia, Applicant submits that Claims 2, 3 and 5-17 are also in condition for allowance.

Claims 1, 2, 11 and 13-17 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0139767 to Jespersen ("Jespersen").

Jespersen discloses an organ or tissue retrieval bag arrangement 10 shown in FIGS. 2 and 7, reproduced below, including a bag 12 having a first or proximal end 14 and a second or distal end 16. The distal end 16 of the retrieval bag 12 has a pair of generally tapered tubular-shaped grasper receiving tips 18 and 20 extending therefrom to receive grasper jaws 34 and 36, respectively. In use, grasper device 32, including retrieval bag 10, is inserted into a patient through a trocar or other opening in the body until the proximal end 14, including beading 28, is received past the distal end of the trocar. The tissue to be excised is next grasped within jaws 34 and 36 of grasper device 32. Once the tissue has been excised, a second grasper device 44 is used to grab beading 28 at the proximal end 14 of retrieval bag 12 and pull retrieval bag 12 in a distal direction about the excised tissue. The specification continues, at paragraph [0041],

> ...The original outer side 48 of the organ retrieval bag 12 thus becomes the inner side of the tissue containment bag once it has been pulled distally from the grasper device 32 and about the tissue/organ "T" being retrieved, as exemplified in FIG. 7. The tissue "T" then may be safely enveloped within the everted organ retrieval bag 12 and removed through the trocar 40 or surgical opening in the patient, without loss of any contaminated fluid or without contaminating tissue components escaping therefrom.

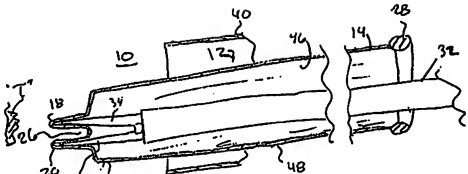


FIG 2

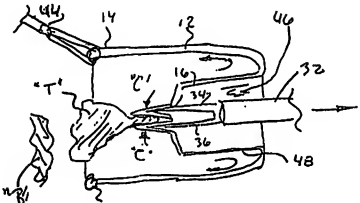


FIG. 7

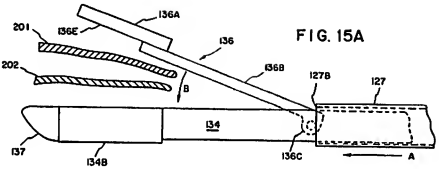
Claim 1 recites, inter alia, "a cover deployment device at least partially disposed about the body portion between the body portion and the elongated cover when the elongated cover is in the first position...". Applicants respectfully submit that Jespersen does not disclose the recited claim elements. More specifically, as discussed above, Jespersen uses a separate grasper device 44 to invert the retrieval bag 12. Contrary to the Examiner's assertion, during normal use forceps 44 is

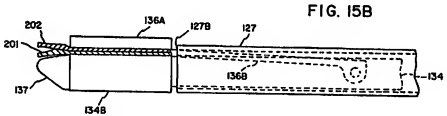
not disposed, even partially, about the body portion of device 32. Furthermore, at no point during use of bag 12 is "cover deployment device" (forceps 44) placed between bag 12 and the body of device 32. Thus, Applicants respectfully submit that independent Claim 1 is patentable over Jespersen and is in condition for allowance.

Claims 2, 11 and 13-17 depend from Claim 1. For at least the reasons discussed above with respect to Claim 1, inter alia, Applicant respectfully submits that dependent Claims 2, 11 and 13-17 are in condition for allowance.

In the Office Action, Claims 30-33 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,318,221 to Green et al. ("Green").

With reference to FIGS. 15A and 15B, reproduced below, Green discloses an instrument having a housing 134 and an anvil member 136. A cartridge assembly 137 is received on a relatively wider section 134B of housing 134. Cartridge assembly 137 includes a plurality of staples (not shown). A collar 127 is slidably positioned over a proximal end of housing 134 and anvil member 136 to approximate the housing and the anvil towards one another.





Applicant respectfully submits that Green does not disclose each and every element recited in Claim 30. More specifically, Green does not disclose a surgical instrument including a shell assembly having a plurality of surgical staples and an elongated cover movable from a first proximal position to a second position to cover the stationary shell assembly. As discussed above, Green discloses an instrument including a housing 134 having a relatively wider distal end 134B configured to receive a cartridge assembly 137. Collar 127 is configured to slide distally to approximate anvil member 136 towards housing 134, and its movement thereby advances over a proximal end of housing 134. However, as shown in FIG. 15B, collar 127 includes a diameter smaller than that of distal end 134B of housing 134 and anvil plate 136A, thereby preventing collar 127 from covering distal end 134B and anvil plate 136. Therefore, collar 127 is not movable from a first position to a second position to cover the portion of housing 134 including cartridge assembly 137 (distal end 134B). Contrary to the Examiner's belief expressed in the

Response to Arguments, the embodiment shown in FIG. 11 of Green, reproduced hereinbelow, does not show an elongated cover movable from a first proximal position to a second position to cover distal end 134B. As evidenced in FIGS. 15A and 15B, above, collar 127 is not intended to cover anvil plate 136A. In this manner, at least a portion of distal end 134B remains uncovered.

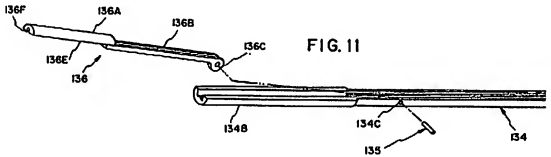


FIG. 11

For these reasons, Applicant submits that Green does not anticipate Claim 30 and that Claim 30 and Claims 31-33 which depend from Claims 30, are in condition for allowance.

Claims 18-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bulow in view of U.S. Patent No. 6,024,741 to Williamson et al. ("Williamson"). Claims 18-20 depend indirectly from Claim 1. Williamson does not provide any disclosure which cures the deficiencies of Bulow with respect to Claim 1 as discussed above. For at least the reasons discussed above with respect to Claim 1, Applicant believes that Claims 18-20 are also in condition for allowance.

Claims 21, 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jespersen. Claim 21 recites the steps of "providing a surgical instrument including...a cover deployment device...the cover deployment device being positioned on the body portion and the cover being positioned about the cover deployment device..." and "moving the cover from the first

position to the second position by advancing the cover deployment device to invert the cover at least partially over the tool assembly...".

Contrary to the Examiner's assertion, a person of ordinary skill in the art would not modify forceps 44 such that they are positioned on the body portion of a surgical instrument, nor would it be obvious to position the forceps between the body portion and the cover. Certainly, the specification of Jespersen is totally devoid of such a teaching or suggestion. Thus, Applicant respectfully submits that independent Claim 21 is patentable over Jespersen and is in condition for allowance. Since claims 25 and 26 depend from claim 21, for at least the same reasons, claims 25 and 26 are in condition for allowance.

Claims 18-20, 22-24 and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jespersen in view of Williamson. Claims 18-20 depend indirectly from Claim 1 and claims 22-24 depend from claim 21. Williamson does not provide any disclosure which cures the deficiencies of Jesperson with respect to Claims 1 and 21 as discussed above. For at least the reasons discussed above with respect to Claims 1 and 21, Applicant believes that Claims 18-20 and 22-24 are also in condition for allowance.

Claim 30 recites a surgical instrument for insertion into a body lumen including, *inter alia*, "a cover deployment member positioned about the elongated body portion between the elongated body portion and the cover". As discussed above with respect to Claim 1, Jespersen fails to disclose a cover deployment member that is positioned about the elongated body portion of an instrument between the body portion and the cover. Williamson does not provide any disclosure which cures the deficiency. Therefore, Applicant submits that Claim 30 is in condition for allowance.

In view of the foregoing amendments and remarks, it is respectfully submitted that all claims pending in the application, namely Claims 1, 2 and 6-26 and 30-33, are in condition for allowance. Accordingly, early and favorable reconsideration of this application is respectfully requested. Should the Examiner feel that a telephone or personal interview may facilitate resolution of any remaining matters, he is respectfully requested to contact Applicant's attorney at the number indicated below.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefor.

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